PREPARATION OF NADA DECISION PACKAGE

1. Purpose:

This guide contains instructions for preparing an NADA (includes Abbreviated New Animal Drug Application--ANADA) decision package.

2. Decision Package for an Incomplete NADA:

a. If the application is incomplete, the package contains a letter to the firm together with all documentation to support the Center's decision. This includes the document summary, and all pertinent specialty reviews, and minutes of meetings or telephone conferences.

b. The letter, signed by the Division Director, should contain the following information:

(1) Introductory paragraph(s) that includes:

(a) the submission date(s) of the original application and any amendments to the original application;

(b) the identification of the product, including the basic use(s) of the drug and the species of animal in which it is to be used;

(c) any previous administrative action on the part of the Agency. For example, if there is a related policy regulation that influences the use of the drug, it should be stated and referenced in this paragraph.

(2) Include conclusions on all elements of the application. Specific elements should be classified as either complete or incomplete. Conclusions and supporting statements should be clear and specific so that the applicant has no problem in interpreting our position. In the event this is a partial incomplete letter, include a statement that the conclusions of the pending review(s) will be forthcoming.

The major elements to be addressed are:

(a) Target animal safety,

(b) Human safety,

(c) Effectiveness - conclusions relative to each claim must be expressed,

(b) Chemistry, manufacturing and controls,

(e) Labeling,

(f) Environmental considerations (either a statement of categorical exclusion or a Finding of No Significant Impact based upon an environmental assessment),

(g) FOI.

Also include any additional comments, conclusions or requirements.

(3) It must be made clear to the applicant that the product is incomplete until satisfactory resolution of the outlined problems is attained. The following sentence should be included in the letter:

"Since NADA _____ is incomplete and unapproved, the product may not be legally marketed."

(4) In closing the letter, always express our willingness to meet with the applicant and discuss the application.

(5) Copies of the letter should be directed to the NADA Original, the primary review Team, and all consulting review Teams.

c. If a subsequent incomplete letter is required, only those issues pertinent to the amendment to the NADA need to be addressed. Dates of previous incomplete letters should be referenced.

3. Decision Package for an Approvable NADA:

The preparation of the approval package is somewhat complex. The following procedures will help to facilitate the process.

a. Drug products used in food-producing animals may require tissue assay methods for residue monitoring purposes. These methods must be reviewed and validated by a government laboratory before an NADA can be approved. The Director, Division of Human Food Safety (HFV-150) is responsible for the review of the tissue residue methods. The Analytical Methods Team (HFV-511) is responsible for the coordination of a method validation trial. The decision package should not be prepared until the method has been validated.

b. As soon as the method has been validated, the application should be forwarded to the Policy and Regulations Team (HFV-6) for preparation of the FEDERAL REGISTER document. The FR writer usually depends upon the content of the approvable labeling for background information. However, time can be saved if the reviewer, especially if requested to do so, takes the time to discuss the NADA and regulation with the FR writer. The following information should be provided to HFV-6:

The name, address, and labeler code of the sponsor; name of the drug as labeled (proprietary and chemical); species and class for which the drug is intended; disease or management conditions for which the drug is intended; if a Type A medicated article, status of Type B & C medicated feeds produced therefrom; warning and caution statements; tolerance or withdrawal period; environmental impact language; generic status of the drug; exclusivity language.

If the approval requires establishing or revising a tolerance, the consulting reviewer in the Residue Chemistry Team (HFV-151) should participate in preparing the draft regulation.

c. The Briefing Memo is prepared by the primary reviewTeam. This memo provides the Center Director or NADE Director with all information relative to the approval. The memo is co-signed by the Division Director and the Team Leader.

d. The approval letter can be prepared based on facsimile labeling, if the final label has not been printed. In the case of draft labeling, a letter requesting Final Printed Labeling (FPL) should be prepared for the signature of the Director for New Animal

Drug Evaluation. This letter, if applicable, can make some comments relative to minor, and only minor, changes in the labeling. If changes other than minor ones in the label are required, the reviewer is reminded to accomplish this through the incompletion process. The approval letter is prepared for the signature of the Center Director.

If an FPL letter is issued and FPL is received, then the Briefing Memo should be amended to indicate that FPL has been received and is acceptable, and an approval letter is prepared for the Center Director's signature.

Instead of requesting FPL prior to approval; another option recently used in CVM and CDER is to issue an approval letter containing a statement that FPL must be submitted to the NADA prior to marketing of the product.

e. The decision package should contain:

(1) Folder A containing only one draft copy of the following documents:

(a) The draft regulation;

(b) Draft Briefing Memorandum;

(c) Draft FOI Summary, with facsimile or final printed labeling;

(d) FONSI and Environmental Assessment, if applicable;

(e) Draft approval letter.

(2) Folder B containing final copies of:

(a) The document summary;

(b) Consulting reviews;

(c) Other pertinent memoranda, telecons, etc.

(3) The Original copy of the NADA submission and open volume.

f. Copies of the approval letter should be made for all Divisions and Teams that have participated in the review process.